

August 20, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 98N-0359, CFSAN Program Priorities for FY2003

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for FY 2003. CSPI is a nonprofit consumer advocacy organization that focuses primarily on food safety and nutrition issues. We accept no industry or government funding and are supported primarily by subscribers to our *Nutrition Action Healthletter* and foundation grants. The following matters are generally listed in the order of the FDA's FY 2002 list of program priorities:

- **Bioterrorism**

We recognize that the events of September 11, 2001 have caused CFSAN to devote large amounts of resources to preventing intentional contamination of the food supply and responding to the requirements of recent legislation. We support efforts to develop and implement threat assessment, emergency preparedness strategies, and particularly to strengthen surveillance of imported foods. We also support sub-strategy 1.1.5, which is to increase coordination with other federal, state and local agencies, but encourage that it be expanded to cover international agencies as well such as the United Nations World Health Organization. While the threat of bioterrorism

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will consume large amounts of the FDA's time and resources, we urge the agency to find creative ways to maintain its traditional mission, which often involves concrete risks from known hazards in the food supply that claim hundreds of lives per year.

- ***Vibrio vulnificus***

The Agency's record on shellfish safety, particularly on measures to control the pathogenic strains of *Vibrio*, has been wholly inadequate. The FDA has repeatedly looked to the industry-dominated Interstate Shellfish Sanitation Conference (ISSC) to resolve this problem. Consumers can no longer afford to have the FDA defer to the ISSC. The Agency has the authority – and the obligation – under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act to protect consumers from this deadly pathogen.

FDA has established as one of its a level priorities for FY 2002 continuing to work with the ISSC to implement a control strategy for *Vibrio vulnificus* in raw oysters (substrategy 1.4.2). While we agree that a control strategy for *Vibrio vulnificus* must be a priority, even higher priority should be given to responding to citizen petition 98P-0504 (substrategy 1.4.3), which requests FDA to establish a performance standard for *Vibrio vulnificus*.

Between 1998 (the year the petition was filed) and 2000, 92 illnesses and 52 deaths linked to *V. vulnificus*-contaminated raw shellfish have been reported by public health officials.¹ Since 2000, at least nine other cases with six deaths have been reported by the media.² The measure adopted by last year's shellfish conference will not impose any controls on *Vibrio vulnificus* until

¹ FDA, *Shellfish-Related Vibrio vulnificus Cases/Deaths, 1989-2000*.

² Michael McLeod, "Making Shellfish Safer to Eat Could End a Way of Life," *The Orlando Sentinel* (July 23, 2001); "State Health Officials Warn Against Eating Gulf Coast Oysters," *The Associated Press*, (June 13, 2002).

2008 at the earliest, so deaths and illnesses will continue. Therefore, to make shellfish safer now, FDA should make as one of its top priorities in the Seafood Safety category granting the citizen petition and proposing a rule establishing a performance standard for *Vibrio vulnificus*.

- **Methylmercury**

FDA's plan to develop an overall public health-based strategy for methylmercury in commercial seafood should be moved from a B* to an A priority. For years, FDA has virtually ignored the methylmercury issue, even though a 1991 National Academy of Sciences (NAS) seafood report revealed fatal flaws in FDA's methylmercury standard,³ and a 2000 NAS report concluded that each year more than 60,000 children are born at risk of neurological impairment because of contaminated seafood their mothers ate while pregnant.⁴

In 2001, the Centers for Disease Control and Prevention (CDC) released data from the first nationally representative sampling of mercury levels in United States women of childbearing age. Ten percent of the women sampled had mercury levels in their bodies high enough to give little or no safety margin.⁵ Raising methylmercury to priority A would demonstrate the agency's commitment to ensure the health and safety of pregnant women and their children.

In addition, the FDA should add as a new A priority responding to a citizen petition, filed over twelve years ago, requesting the agency to set a regulatory limit for methylmercury in fish.

³ National Academy of Sciences, *Seafood Safety* (1991).

⁴ National Academy of Sciences, *Toxicological Effects of Methylmercury* (2000).

⁵ Centers for Disease Control and Prevent, *Blood and Hair Mercury Levels in Young Children and Women of Childbearing Age-United States, 1999*, 50 Morbidity and Mortality Weekly Report 140, 141 (2001).

In July 2000, CSPI again petitioned FDA to act on this important public health issue.⁶ However, despite the 2000 NAS report and the 2001 CDC data adding to the body of science showing the adverse effects of low-level methylmercury exposure on developing fetuses, FDA still has yet to act.

CFSAN also should, under its “Education” priorities, elevate its goal of conducting education and outreach on methylmercury in seafood to heavy fish-eating audiences in selected states (sub-strategy 1.12.3) to an A priority, particularly since the FDA has not taken sufficient regulatory action on this issue.

- **Egg Safety**

CSPI has long been an advocate of mandatory national farm-to-table egg safety standards to address the public health threat of *Salmonella enteritidis* (SE) in raw or undercooked eggs. Although the Egg Safety Action Plan identified FY 2002 as the deadline for a final rule adopting a nationwide SE reduction program for egg production, FDA has taken no action to date to adopt on-farm controls for shell eggs.

Eggs contaminated with SE cause an estimated 660,000 illnesses and 300 deaths in the United States. Outbreak data compiled by the CSPI for its publication, *Outbreak Alert!* shows that eggs have been implicated in over 200 SE outbreaks between 1990 and 2001. Accordingly, the FDA should make the issuance of a proposal and finalization of on-farm risk-reduction measures for shell eggs a top priority.

In a letter to CSPI dated June 14, 2002, Dr. Crawford affirmed that FDA’s goal to publish

⁶ CSPI, *Petition to Set a Regulatory Limit for Methylmercury in Seafood That Reflects the Risk to Pregnant Women and Children from the Intake of Seafood Containing Methylmercury*, filed July 17, 2000.

a proposed rule addressing on-farm risk-reduction measures for shell eggs remains a “high priority.” Accordingly, the item listed as sub-strategy 1.6.2, “Publish proposed egg safety rule for farm and retail,” should be given the top priority within this program. We urge the FDA to implement and enforce mandatory on-farm SE controls that include environmental testing and diversion after a SE-positive result.

- **Listeria monocytogenes.**

The priorities for *Listeria* indicate that FDA intends to focus on the collection of additional data for and rewriting of the *Listeria monocytogenes* risk assessment in ready-to-eat foods. The item listed as a “B*” – developing draft guidance advising processors on steps to reduce *Listeria monocytogenes* contamination in ready-to-eat foods -- should be elevated to an A priority level. Protection of the public should not await completion of the risk assessment.

L. monocytogenes remains one of the most serious foodborne pathogens. Listeriosis is associated with higher hospitalization rates than any other pathogen⁷ and had the highest case-fatality rate in 1999 of the FoodNet pathogens.⁸ Over the past 10 years, outbreaks of listeriosis have been documented in FDA-regulated foods, including chocolate milk and queso fresco cheese. The chocolate-milk outbreak sickened 69 individuals living in parts of three states.⁹ In the queso-fresco cheese outbreak, there were 12 reported cases. Ten of these cases were

⁷ Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 2000 (Preliminary Report)*, Sept. 2001, at p. 10 (reporting that 90% of reported cases were hospitalized).

⁸ Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 1999 (Final Report)*, Nov. 2000, at 5, 12.

⁹ Centers for Disease Control and Prevention, *U.S. Foodborne Disease Outbreaks*, available at <http://www.cdc.gov/ncidod/dbmd/oubreak/us_outb.htm>.

pregnant women, five of whom lost their babies because of still births from *L. monocytogenes* infection.¹⁰

Therefore, FDA should make it a priority to require plants producing FDA-regulated foods at risk for *L. monocytogenes* (such as soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads) to test their environments and final products for the presence of the pathogen. This would help to minimize consumer exposure to *L. monocytogenes* at retail.

- **Transmissible Spongiform Encephalopathies (TSEs)**

Although FDA lists three goals under the TSE program area, the agency has failed to identify any of these as an A priority. Scientists have documented that if a cow has BSE, consuming small portions of its brain, spinal cord and other central nervous system (CNS) tissue could cause human cases of variant Creutzfeldt-Jakob Disease (vCJD).¹¹ Although BSE has not been detected in U.S. cattle, its absence cannot be confirmed with certainty. Therefore, there is an overwhelming need to institute all reasonable public health precautions to prevent vCJD in the event that U.S. cattle are infected with BSE.

Because the brain and spinal cord are the most infective portions of cattle, and risk of infection from BSE increases with a cow's age, the FDA should make it a top priority to cooperate with USDA to develop a regulatory approach to minimize human exposure to BSE

¹⁰ Centers for Disease Control and Prevention, "Outbreak of Listeriosis Associated with Homemade Mexican-Style Cheese - North Carolina, October 2000-January 2001," *Morbidity and Mortality Weekly Report*, Vol. 50, No. 26, pp. 560-62.

¹¹ Paul Brown, et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns*, 7 *Emerging Infections Diseases* (Jan.-Feb 2001), pp. 6, 10.

from the use of bovine brain, spinal cord, and eyes from animals 24 months or older in CFSAN-regulated products.

Recent reports concerning the spread of chronic wasting disease (CWD) in eight states among wild deer and elk, as well as farmed elk, make it imperative that the FDA work with the USDA to quickly develop a regulation prohibiting the use of any part of an elk or deer exposed to CWD from CFSAN-regulated products. Because there are currently no regulations governing how deer carcasses are handled, regulations should be adopted as soon as possible to assure that no parts of animals exposed to CWD find their way into CFSAN-regulated products.

Banning the use of bovine materials from BSE or BSE high-risk countries in CFSAN-regulated products also is crucial. In December 2000, the USDA's Animal and Plant Health Inspection Service (APHIS) banned all imports of rendered animal proteins, regardless of species, from countries listed as BSE-positive or presenting a high risk of introducing BSE into the USA. While the FDA has issued import alerts, it has instituted no outright ban against the use of bovine material from BSE or BSE-high-risk countries in CFSAN-regulated products. We urge FDA to alter its priorities in this area and reclassify the goals relating to TSE's to category A.

- **Acrylamide**

Acrylamide contamination of food may be causing thousands of cases of cancer per year. The FDA should measure acrylamide levels in a wide variety of foods sold in the U.S. and devise strategies for their reduction. The agency should inform the public about dietary modifications or changes in cooking methods that should be made in response to its research. The FDA should also be seeking ways of preventing acrylamide formation in various food categories. These matters should be placed on the agency's priority list.

- **Potassium Bromate**

The FDA has known since 1982 that potassium bromate can cause tumors of the kidney, thyroid, and other organs in animals. Subsequent studies on rats and mice confirmed that it causes tumors of the kidney, thyroid and other organs. On July 19, 1999, CSPI petitioned the FDA to ban bromate. FDA lists Bromate as a B priority in its 2002 Program Priorities (sub-strategy 2.1.3), but has taken no public action to respond to our petition to restrict the use of this additive. We urge that this matter be given higher priority.

- **Sorbitol and Mannitol**

In September 1999, CSPI petitioned the FDA to require foods containing one or more grams per serving of sorbitol or other sugar alcohol, such as mannitol, to carry a better warning label that the foods may cause severe diarrhea and are not suitable for consumption by children.¹² The FDA should accord this petition priority attention.

- **Salatrim**

As discussed in our 1998 petition to the FDA, Salatrim may cause diarrhea in humans and products containing this ingredient may be misbranded.¹³ The FDA has taken no action on this matter. We urge that it be given priority attention.

- **Carmine/Cochineal**

CSPI is pleased to note that for 2002, the Agency gave a B priority to developing a proposed rule to require the declaration of carmine/cochineal extract, a color additive, on

¹² *Petition to Improve the Existing Warning Label on Processed Foods that Contain the Sugar Substitute Sorbitol* (Sept. 27, 1999).

¹³ *Petition to FDA on the Generally Recognized as Safe (GRAS) Status of Salatrim* (June 19, 1998).

products containing it (sub-strategy 1.11.6). As we stated in our 1998 petition, carmine/cochineal extract may cause severe allergic reactions in humans. The issuance of this proposal should be upgraded to the FDA's A list.

- **Quorn Mycoprotein**

We urge the FDA to give priority attention to banning the sale of this product for the reasons set forth in our letters to the agency of August 12, 2002 and April 24, 2002. This product has caused serious health problems including anaphylaxis, severe vomiting, and diarrhea. It should be removed from the market.

- **Allergens**

On May 26, 2000, nine state attorneys general petitioned the FDA to combat food allergen problems with new labeling and stricter good manufacturing practices. This was a highly unusual action for attorneys general. The attorneys general urged the changes "to ensure the safety and welfare of the five million U.S. citizens possessing food-related allergies."¹⁴ The petition states that ambiguous or insufficient labeling has caused serious consequences, including death. Although FDA held a hearing on issued on July 25, 2001, and listed a proposed rule as B* on the 2002 priority list (sub-strategy 1.11.7), little concrete action has been taken.¹⁵ This matter should be elevated to an A priority. We further urge that level A priority attention continue to be given to developing and implementing an allergen enforcement strategy to prevent cross-contamination (sub-strategy 1.11.2).

¹⁴ Petition from Nine Attorneys General, 00P-1322, May 30, 2000.

¹⁵ FDA, CFSAN 2002 Program Priorities at 1.11.7.
<<http://www.cfsan.fda.gov/dms/cfsa102b.htm>>.

- **Caffeine**

In 1997, CSPI and academic experts petitioned the FDA to require quantitative labeling of caffeine, as well as to perform a scientific review of the health effects of caffeine to determine if stronger measures should be taken to protect the public from its adverse effects.¹⁶ The American Medical Association also has called for quantitative labeling of caffeine content.

Other countries have already begun to take steps to protect their consumers. By July 1, 2004, products sold in the European Union containing more than 150 milligrams of caffeine per liter must include the term “high caffeine content” near the product name. Such products must also indicate the caffeine content expressed in mg/100 ml.¹⁷ Furthermore, Australia requires that energy drinks (formulated caffeinated beverages) state: “Not suitable for children and caffeine sensitive persons.”¹⁸ The FDA, too, should recognize health concerns due to caffeine and take the actions we have recommended to protect American consumers.

- **Functional Foods**

The FDA should enforce the food additive provisions of the law and prevent companies from adding herbal medicines and other novel ingredients to foods that are not Generally Recognized as Safe (or approved as food additives). Dietary supplements must not be allowed to masquerade as foods in order to avoid sections of the law pertaining to food additive approval. Thus we support sub-strategy 2.1.3 and urge that it remain an A priority.

The FDA should also respond to the CSPI petition seeking implementation of the

¹⁶ Center for Science in the Public Interest, *Petition for Amendment of Food Labeling Regulations to Require Quantitative Ingredient Labeling of Caffeine Content and Request for Review of Health Effects of Caffeine*.

¹⁷ Commission Directive 2002/67/EC, 2002 O.J. (L 19) 191.

¹⁸ Australia New Zealand Food Standards Code Standard 1.2.3. clause 2.

recommendations contained in a report by the General Accounting Office.¹⁹ Among its numerous recommendations, the GAO report concluded that regulations be adopted on the safety-related information required on labels; the nature and extent of evidence companies need to adequately support structure/function claims; a notification procedure prior to the use of novel ingredients; and the use of the same disclaimer as is currently required on dietary supplements. It also called for the establishment of an advisory committee to reevaluate the current labeling approaches for foods with novel ingredients to determine whether the distinctions between structure/function and health claims are understood by consumers and identify other changes needed to improve consumer understanding of health-related claims.

- **Dietary Supplements**

We support maintaining at A level sub-strategy 2.3.5, which is to take enforcement action against supplement ingredients that raise safety problems. We also support efforts by the agency to initiate targeted research programs on dietary supplements where there are significant safety concerns. Although this is currently listed as a B* priority (sub-strategy 3.2.5), it should be elevated to an A priority. Further, the FDA, should expand the National Academy of Sciences study of dietary supplement safety. More products should be covered and the study should be expanded to efficacy as well.

The FDA is burdened with a weak law that limits the agency's authority to protect the public from unsafe and misleadingly labeled supplements. Recently, members of Congress have introduced, or called for new legislation. The FDA should, upon request, provide information detailing the need for a new approach to dietary supplement regulation.

¹⁹ CSPI, *Petition for Rulemaking on Functional Foods and Request to Establish an Advisory Committee*, Docket No. 02P-0122/CP1. Mar. 21, 2002.

The FDA should also revise its final rule on structure/function claims for dietary supplements to prohibit claims identical to those used on over-the-counter drugs (which have been approved as safe and effective).

- **International Affairs/Food Safety**

The FDA should encourage that the Administration's trade policies further the objectives of the Act. The FDA should ensure that public health takes precedence over trade concerns and should urge that international standards be harmonized upward. These factors should be taken into account as the agency finalizes guidance for equivalency determinations (sub-strategy 3.3.5) and when the agency takes positions on behalf of the U.S. government delegation to Codex meetings. The agency should also promptly respond to the recommendations of the Trans-Atlantic Consumer Dialogue.

- **Biotechnology**

The FDA should give priority attention to completing a final rule for a mandatory notification program for bioengineered foods and ingredients. The agency should take final action on its proposal to regulate the labeling of foods developed, and not developed, through the use of biotechnology. We urge the agency to finalize the proposed rules and enforcement policies in accordance with the detailed comments that we have submitted on these measures. These measures should be raised from their current B* level priority to A level priority.

- ***Trans* Fatty Acids**

We urge that the FDA give A priority to publishing a final rule requiring the disclosure and establishing a percent Daily Value for *trans* fatty acids for the reasons most recently communicated to the agency in our letter of August 14, 2002. We further urge the agency to finalize its proposed rules for health and nutrition claims pertaining to *trans* fatty acid content.

- **Added Sugars**

The FDA should give priority attention to proposing a rule that would require the listing of amounts of both total and added sugar content, along with the percentage of a newly designated Daily Value for added sugars as described in our previous petition to the agency. The grounds for this request is set out fully in our 1999 petition to the agency.²⁰

- **Percentage Ingredient Labeling**

CSPI has petitioned the agency to extend percentage-ingredient labeling to all foods. QUID is necessary for consumers to compare the relative amount of ingredients between seemingly similar products. In the EU, Australia, and New Zealand, QUID requirements are already in place. FDA should work with Working Group of the Codex Committee on Food Labeling that has been formed to develop an international standard for QUID.

- **Misleading Ingredient Claims**

Enforcement of the FDA's food-labeling requirements has waned in recent years. As a result, misleading claims on food labels are increasing. We urge the agency to enforce the law with particular attention to misleading claims pertaining to healthful ingredients such as whole wheat, fruits and vegetables. Violations of the Act that cannot be handled by the FDA due to resource constraints should be systematically delegated to state enforcement agencies.

- **Health Claims**

FDA should issue regulations in accordance with the U.S. Court of Appeals decision in *Pearson v. Shalala* that require all health claims not supported by significant scientific agreement

²⁰ *Petition for Proposed Rulemaking to Establish a Daily Value for "Added Sugars," to Require Nutrition Labeling of "Added Sugars," and to Make Corresponding Changes to Nutrient Content and Health Claim Regulations*, (Aug. 3, 1999).

to state immediately before such claim, and in lettering as large and conspicuous as the claim, the following statement: “The Food and Drug Administration does not consider the following statement to be scientifically valid.”

The FDA should also propose implementing regulations for the health and nutrition claims sections of the Food and Drug Administration Modernization Act of 1997. Those regulations should require public docketing of all health claim notifications and confirm that all health claims for foods must be supported by significant scientific agreement. In addition, such regulations should specify that health and nutrition claims based on authoritative statements of other government agencies are limited to statements that were intended to constitute dietary recommendations.

The FDA should cease approval of product-specific health claims for breakfast cereals and other specific foods. Such claims provide consumers with potentially misleading dietary advice that is not supported by the public health community.

- **Food Standards**

The FDA lists the development of a proposed rule on guiding principles for standards of identity as a B* priority (sub-strategy 3.6.3). This matter should be dropped. The initiative is not supported by consumer organizations and some segments of the food industry. In an era of limited resources, the effort should be terminated.

CONCLUSION

CSPI appreciates the opportunity to comment on CFSAN's priorities for FY 2003. The issues the FDA chooses to give priority attention to will have a vital impact on the health and well-being of all Americans.

Sincerely,



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